DR200/HE Holter Recorder
User Manual

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advancing Holter technology

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Chapter 1 -Introduction

The data obtained by the DR200/HE Holter recorder is not analyzed at the time of recording. After the recording is complete, the data must be uploaded to a 5.2 or newer versions of the NorthEast Monitoring, Holter Analysis software.

Clinical Benefits:

The DR200/HE Holter Recorder is a portable, wearable device that is used to assist in the diagnosis of heart issues that do not show up on an electrocardiogram.

The DR200/HE is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

The DR200/HE Recorder is not for In Vitro diagnostic use.

Specifications

Physical Specifications

The DR200/HE Holter Recorder meets the following physical specifications:

- Size: 8.6 cm (length) x 6.0 cm (width) x 2.0 cm (depth)
- Weight: 70.9 grams (2.5 oz.) without battery; 99.3 grams (3.5 oz.) with battery

Electrical Specifications

The DR200/HE Holter Recorder electrical specifications are:

- Recording bandwidth: 0.05 to 70 hertz in 180 samples/sec. mode.
- Operation duty cycle: Continuous.
- Data storage format: Sample difference.
- Pacemaker sensitivity: 2 millivolts.
- Pacemaker pulse duration: 150 to 2,500 microseconds.
- Resettable fuses: 0.5 amp

Power Supply

The DR200/HE Holter Recorder is powered by one 1.5 volt AA battery, not included. An AA alkaline battery (MN1500 or the equivalent), a AA rechargeable NiMH (nickel metal hydride) battery, or AA Eveready Lithium L91 battery can be used. Although battery life may last longer than a recording, batteries should not be re-used for a second patient. After one use, they should be disposed of following local ordinances.

Do not leave battery in the recorder for extended periods (more than two weeks) when the recorder is not in use.

If you use rechargeable batteries, the battery recharger should be kept out of the patient environment and hook-up area. For details about recommended batteries/chargers, see Appendix C.

Environmental Specifications

This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

The operating range of the device is between 10 and 45 degrees C, between 10 and 95% humidity, and between 700 and 1060 hPa pressure.

Store and/or transport the recorder at temperatures between -40 and 70 degrees C, between 10 and 100% relative humidity, and 500 and 1060 hPa pressure.

The recorder has an Ingress Protection Marking of IP22. The solid particle protection is level 2 as the device is protected against objects > 12.5mm, such as fingers or similar objects. The liquid ingression protection is level 2, which meant that vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.

Intended Use

The DR200/HE Holter Recorder is intended to be used for Holter recording for the detection of arrhythmias and efficacy of pharmacological treatment.

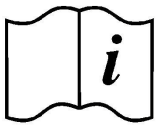
Indications for Use

Detection of Arrhythmias: The DR200/HE Holter Recorder is indicated for use in continuous recordings of cardiac rhythm when intermittent arrhythmias are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.

Efficacy of Treatment: The DR200/HE Holter Recorder is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.

Symbols

Please note that the recorder is labeled with the following symbols:



Refer to instruction manual/ booklet. Follow instructions for use

Type BF device.

This device contains an internal lithium battery that may be recycled at end of life. This device and all other accessories should be disposed of according to local ordinances.

This product does not contain lead.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Medical Device

The DR200/HE is covered by one or more US patents: D889, 662, D905, 253, 6125296, 6666182.

Recorder Package Includes:

- DR200/HE Recorder
- Memory card
- Holter pouch
- Patient lead wires

LCD Display

The recorder has an LCD screen that is used to display either time-of-day (during the recording), prompts and error messages (during the hook-up procedure or during recording), or lead quality (during the Holter hook-up procedure). For details about the information displayed on the LCD, refer to the hook-up directions that follow.

Instructions to the User About Electrical Interference

This equipment has been tested and found to comply with the limits for a Class-B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment has been certified to comply with the limits for a Class-B computing device, pursuant to FCC Rules. In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

Using Patient Lead Wires

The recorder is compatible with standard single-use silver/silver-chloride ECG electrodes. The patient lead is comprised of shielded patient wires (cables) with either seven leads or five leads for a 3-channel Holter recording, or three leads for 2-channel Holter recording. The patient lead wires connects to the recorder via a 7-pin in-line receptacle.

Patient electrodes should not be applied to anything except the patient. Patient electrodes should be left sterile in their original packaging until use. Follow manufacturer's instruction for use, and discard after use. Dispose of electrodes following local ordinances and the manufacturer's instructions.

Note: Do not pull on or stretch the patient lead wires when you clean them. This can cause premature failure. Instead, lay the attached wires on a clean, flat surface, hold them down with one hand, and holding a cloth in the other hand, rub all surfaces of the cable.

Patient lead wires should be visually inspected between uses for worn or cracked areas. Frequently used wires should be replaced at least every 6 months. Worn wires should be replaced before next use and disposed of following local ordinances and manufacturer's instructions.

See Appendix A for details about cleaning and disinfecting the recorder and lead wires as needed.

Storage Capacity

The patient's Holter data is stored in the recorder on a removable SD Card. To store 24 hours in normal mode, the minimum capacity of the SD Card should be 28 megabytes; 56 megabytes are required for 24 hours in high resolution mode.

There are some SD Card types that may draw excessive power, and will therefore drain the battery prematurely. If you purchase cards from a supplier other than NorthEast Monitoring, it is recommended that you first test the SD card for a greater amount of time than the expected use.

The patient's Event data is stored in non-volatile memory internal to the recorder.

Warranty Repairs

The warranty for NorthEast Monitoring products can be found on our web-site at www.nemon.com. Contact your dealer or NorthEast Monitoring prior to returning a recorder for repair to determine the warranty period, conditions and exclusions. If your dealer is unavailable, contact NorthEast Monitoring directly.

The recorder can only be serviced or repaired by NorthEast Monitoring or a NorthEast Monitoring authorized representative.

Prior to returning a recorder, you must obtain a return merchandise authorization (RMA) number. This RMA number must be visible on the outside of the packing carton, otherwise, NorthEast Monitoring will refuse delivery. The usable life of the device and accessories are at least long as the warranty period.

Operating the Recorder

If you require assistance in setting up, using, or maintaining your recorder, contact NorthEast Monitoring or your dealer. Should the recorder fail to work properly during its useful life or changes its performance, stop using immediately and contact NorthEast Monitoring or your dealer.

The DR200/HE Holter Recorder contains no user-serviceable parts. Removing the label or opening the recorder voids the warranty.

NorthEast Monitoring can be contacted at: [+1]978-461-3992, toll-free in the U.S.A. at 866-346-5837, or email support@nemon.com.

Care should be taken when this device is used, especially with infants or small children, as it includes small internal parts that could be a choking hazard. Additionally, the lead could become entangled and could be a strangulation hazard.

Online help

In addition to the information in this manual, more information and help can be found at our web site, www.nemon.com or by emailing technical support at support@nemon.com.

Our "Technical Support" page on the web-site includes Frequently Asked Questions.

The most current version of this manual, the warranty and our software can always be found on our web-site on the "Downloads & Documents" page.

Report Serious Incident

The user and/or patient must report any serious incident that has occurred in relation to the Holter Monitor should be reported to North East Monitoring and the applicable competent authority / government agency in the country where the incident occurred.

Chapter 2 - Holter Recording

To use a DR200/HE Holter Recorder to record a patient's long-term ECG (Holter), follow the appropriate steps listed below:

Step 1 - Hook-up patient;

Step 2 - Prepare the recorder

Step 3 - Enter patient ID on recorder;

Step 4 - Start recording.

These steps are described in detail starting with the next section.

If you have a new SD Card that has not been formatted with a flash.dat file, you will need to use your NorthEast Monitoring, Inc. Holter Analysis software to initialize the card for the first time.

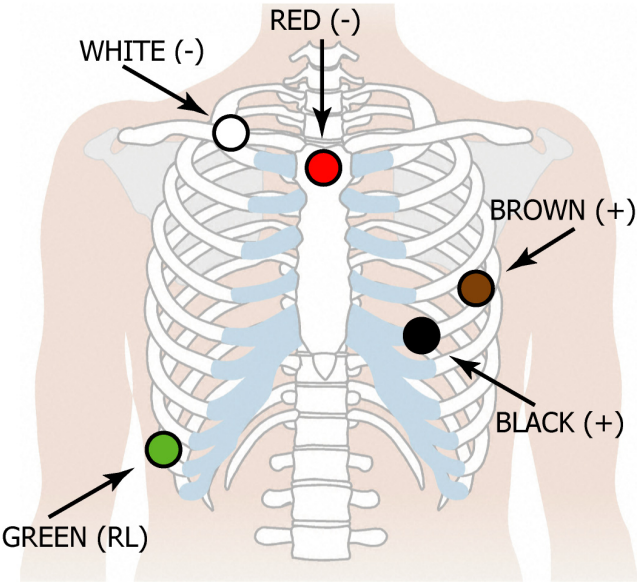
When the recording is finished, simply remove batteries to stop recording.

Step 1: Hook-up Patient for Holter

The most important element in Holter monitoring is recording a clean long-term ECG signal. Because a clean signal is directly dependent on the hook-up procedure, great care should be taken when hooking up the patient. Poor hook-up causes poor signal quality and artifact.

To ensure proper hook-up, follow these steps:

1. Using either the 5-Lead (3-channel) or 7-Lead (3-channel) hook-ups shown, identify sites for the electrodes.
2. Prepare the patient's skin. If the patient has hair in any of the electrode areas, shave it with a safety razor. Use an alcohol pad and rub the sites briskly until the skin reddens. Let the skin air dry before proceeding.
3. Attach the patient cable to the recorder. Next, snap a lead wire from the patient cable to each of the electrodes.



5-LEAD PLACEMENT

5-LEAD PLACEMENT

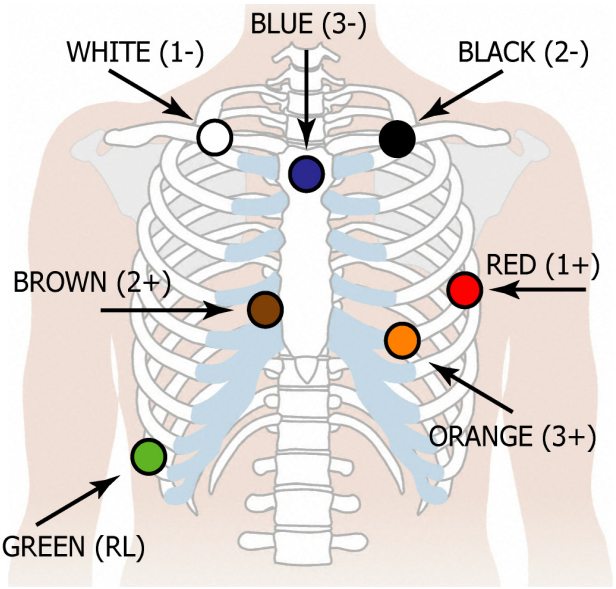
Channel 1:
+ Brown 5th rib, left anterior axillary line
- Red centered

Channel 2:
+ Black 5th rib, left of mid-clavicular line
- Red

Channel 3:
+ Black
- White right manubrium

Ground:
Green centered over rib

Note: The 7-lead hook-up shown below consists of independent bipolar leads and complies with IEC60601-2-47 requirements (Code 2). The 5-electrode hook-up does not have independent leads, and so, does not correspond to either Code 1 or 2, but is widely used in the United States and Canada.



7-LEAD PLACEMENT

7-LEAD PLACEMENT

Channel 1:
+ Red 5th rib, left anterior axillary line
- White right manubrium

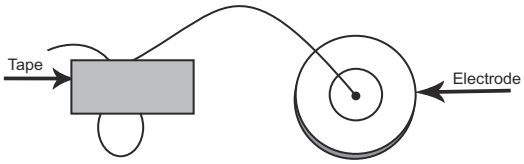
Channel 2:
+ Brown 2 cm. right of xiphoid process
- Black left manubrium

Channel 3:
+ Orange 5th rib, left of mid-clavicular line
- Blue centered on manubrium

Ground:
Green centered over rib

4. Attach an electrode at each of the patient's prepared sites. As you attach electrodes, be careful to not let any unattached electrode come in contact with other conductive objects, including ground. Be sure to refer to the diagrams on the previous page for correct placement of each colored lead. The electrodes should be placed over bone at each of the sites. Press the center of each electrode against the patient's skin, then rub the outer circle of each electrode to secure it.
5. If you use lead lock or clip lock electrodes, be sure to use the lock or clip to relieve stress on each lead wire; refer to the diagram at right for proper use. Otherwise, tape each lead wire into a stress loop (see the diagram below) to help prevent movement of the electrode.

Using a clip lock electrode



Stress Loop

Step 2: Prepare the Recorder

After connecting the patient to the recorder, follow these steps to prepare the recorder:

1. Remove the battery cover from the back of the recorder. The battery compartment and the SD Card slot are now exposed.
2. With the recorder front facing up and away from you, insert an SD Card into the slot. The SD Card should have the connector contacts down and toward the recorder as you gently push it in. Be sure to use the SD Card you formatted for this patient.

   If the card pops out slightly when you push it in, try again. **Pushing gently on the card both inserts it and allows you to remove it. Never pull the card out as it will damage the recorder.**

Note: The SD Card should slide in easily. Make sure you do not force the card in; if you force the card in upside-down or force the card out by pulling, it can damage the connector inside the recorder.

3. Insert a fresh 1.5 volt AA battery into the battery compartment, being sure to orient it as indicated in the diagram inside the compartment. See Appendix C for details about battery choices.
4. Replace the battery cover by sliding it into the card slot until it clicks.
5. "DR200/HE" will first appear on the screen and then the NorthEast Monitoring information will appear. Press ENTER to continue.
6. If you did not erase the previous patient's data from the SD Card, you will now be prompted to Erase memory. Use the green arrows to select "*Yes" and press ENTER.
7. You will see ERASE DONE when erasing is complete.

Note: If at any time you need to restart the set up process, just remove the battery to begin again.

Step 3: Enter Patient ID

You will now see a screen with two choices: "New Patient" and "Settings". Since the recorder will store settings between patients, you may only need to adjust settings when

there is a time change or if you want to change between Holter and Event. For more information on adjusting settings, refer to Chapter 4 - Recorder Settings and Messages.

1. If you would like to input the Patient ID at this time, press ENTER and use the green up arrow to select the first character of the ID. Use the ENTER button when you have entered the first character and continue until all of the ID is entered. Once the patient ID is entered, press the EVENT button.

Note: If you make an error while entering a character into the Patient ID, you can backspace one or more times by holding down the Enter key for several seconds until the cursor moves to the left.

2. Now, the LCD will display the ECG signals, the battery level, and lead quality based on the level of impedance detected between the two electrodes for each channel. Lead quality for each channel is a number between 0 and 5. The best possible signal quality reading is 5; that indicates a good electrode-skin connection. A "0" indicates no signal is being received by on the recorder.
3. Once a satisfactory lead quality signal of 3 or more is displayed for all channels, continue with the final step - Start Recording.

Note: If you do not push the EVENT button, the recorder will display lead quality for 10 minutes, then start recording. To delay the start of recording, simply press the EVENT button briefly and the 10-minute countdown will start again.

Step 4: Start Recording

1. Once the LCD displays satisfactory lead quality signals for all channels, you can start the recording by pressing the EVENT button for 3 seconds till you see "Recording Started". If you do not do this, recording will begin automatically after 10 minutes. During recording, time-of-day appears on the LCD. Once recording begins, it will continue until the battery is removed or the SD Card is full.
2. The patient can choose between a belt clip or pouch with strap. All equipment, except the electrodes and a portion of the lead wires, should be over at least one layer of clothing so that it is not in direct contact with the patient's skin. Orient the recorder on the patient so that the EVENT button is accessible and the LCD is visible.
3. Advise the patient to not expose the recorder or electrodes to any wet environment; in addition, they should not shower, bathe, or swim while wearing the recorder.
4. Instruct the patient on how to use the EVENT button to indicate symptomatic events or activities of interest during the Holter test. Advise them to push the EVENT button briefly. The patient may also be given the opportunity to enter a diary at the time of the event. They should use the up/down arrows to choose the most appropriate entry.

   The EVENT button then marks the recording so that when the Holter signal is analyzed, the ECG at the time-of-day the button was pushed is kept as saved strips and labeled as an event and with the selected diary entry.
5. When the patient returns, remove the electrodes, leads and recorder from the patient. Open the recorder and remove the battery and SD Card from the recorder. **Pushing gently on the card both inserts it and allows you to remove it. Never pull the card out as it will damage the recorder. T**he Holter signal is now ready to be analyzed.

Power Loss Protection Feature

In Holter recording mode, as of software version 4.41, if the battery is removed and reinserted within 12 hours, the recording will continue. (As of firmware version 1.09, restart

time is up to 60 minutes, but for firmware versions 1.08 and earlier, it is only up to 10 minutes.)

When the battery is reinserted during the allowed time, the LCD returns to the time-of-day and continues to record the patient's Holter signal. When the patient's recording is analyzed, the signal recorded while the batteries were not in place appears as continuous high-frequency artifact in all channels.

If the battery is left out for more than 12 hours, recording cannot be restarted. Instead, you will have to use the recording as is, or you will have to re-initiate the recording after erasing the memory on the SD Card.

Note: If the SD Card has been removed and you wish to restart the recorder without a card in order to update settings, you will need to press the following buttons in this exact order during the 15 second countdown: ENTER, down arrow, up arrow, EVENT.

Chapter 3 -Recorder Settings, Error Messages and Troubleshooting

Recorder Settings

For Holter recording, you can adjust settings on the recorder between patients only. To begin, insert a battery to start the recorder.

If 15-second countdown occurs

If your recorder is in Event mode, the 15-second countdown will begin when you put in a new battery. To interrupt the 15-second countdown, quickly press ENTER, down arrow, up arrow and then EVENT, in that order. You should now see the NorthEast Monitoring screen. Press ENTER to continue to move to the main menu.

To Adjust Settings

To adjust the settings, use the green arrows to move up and down between the menu items and ENTER to accept. The cursor ">" will appear next to the item that you are able to update. Press ENTER to begin updating that item, and then use the green arrows to adjust the value. When finished adjusting a value press ENTER to save the value. To return to the previous menu, use the green arrows to move the arrow to "Return" at the top of the menu and press ENTER.

To Review Settings

At any time, you can remove the battery from the recorder and re-insert. Then interrupt the 15-second countdown as instructed above.

To Update Time and Date

The recorder should save the correct time and date between uses, but if you ever need to update the time or the date, move the cursor to "Time and Date" and press ENTER. You can now update Hour, Minutes, Day, Month or Year by moving the cursor with the green arrows and pressing ENTER.

About

To view the Serial No, the customer code (cc), the Version number of the software on the recorder, the build number for that software, and the number of times the recorder has been used in Holter mode.

To Update General Settings

Contrast. Use arrows to increase or decrease contrast.

Lead Loose.

- On - Lead Loose message is enabled.
- Off - Lead Loose message is disabled.

Event marker. When on, the ECG will be labeled with one second of 6-cycle square wave where the event took place.

Key mode.

- Normal - Sound enabled and no delay;
- Delayed - Patient will need to press Event and Enter buttons for several seconds in order to prevent false entries, and sounds enabled; or
- Quiet - Sound disabled. No delay.

Rec Type. Set to "Holter" for Holter recording.

Menu Lock. Menu Lock will prevent anyone from reviewing or updating any other settings.

- **To lock the menu, enter 217.**
- **To unlock the menu, enter 151.**

Language. Select from U.S. English, International English, Danish, Finnish, German, French, Italian, Norwegian, Polish, Portuguese, Russian, Spanish and Turkish.

Diary. When the Diary is turned On, the patient will be able to select a symptom during a manual event. During Event recording only, Post Event Seconds must be is set to 30 or greater, for the Diary options to be displayed to the patient.

Hi Res / ch: For release 4.46, only 3 channel and Hi Res recording function correctly. Holter 1 & 2 channel should not be used.

When turned On, the recorder will record Holter in high resolution. High resolution mode provides enhanced R-wave reproduction for pediatric recordings.

Error Messages and Troubleshooting

If you see the time-of-day on the recorder screen, the recorder is recording.

Note: If the LCD screen is completely blank, this means that the recorder is not recording.

An error message will appear when there is a problem with the recorder. The recorder may display the following error messages:

Battery LOW: Battery is running low. When this message first appears, you will have about 5 days of recording time left on your battery.

Battery FAILURE: Recording has stopped.

Card Erase ERROR: An error was found while attempting to erase the SD Card. This usually means a defective card.

LEAD LOOSE: This error will occur when there is a problem with the patient hook-up. The problem may be with an electrode, a lead or the cable that connects the leads to the recorder. The LEAD LOOSE message will remain on the screen for about 10 seconds after the problem has been corrected. This error message can be turned off in General Settings.

Missing SD Card: There is no SD Card in the device. A card is required for Holter recording.

SD Access: Unable to read the SD Card. This usually means a defective card.

SD Card is write locked: Write Lock tab is set on the SD Card. Unlock Write Lock tab and try again.

SD Setup Failure: Failure during write of patient ID to SD Card. You will need to re-initialize your card using the Holter Analysis Software.

SD Card Incorrectly erased: There may be disallowed files on the SD Card. Remove SD Card from recorder and use card reader and Windows Explorer to identify and delete these files. The only file allowed is flash.dat.

Short recording: There are some SD Card types that may draw excessive power, and will therefore drain the battery prematurely, resulting in a short recording. If you purchase cards from a supplier other than NorthEast Monitoring, it is recommended that you first test the SD card for a greater amount of time than the expected use.

Unable to write SD: An error was found while attempting to write to the SD Card. This message occurs when the card is full. Sometimes this message will appear when a card is defective.

Write Timeout error: This usually means a defective card.

Chapter 4 -Appendices

Appendix A: Maintenance and Care of the Recorder

Always remove the battery before cleaning the recorder.

Clean the outside of the recorder with a damp soft cloth between uses; use water and a non-abrasive liquid soap, as required. DO NOT use any abrasive cleaners, such as acetone, on the outside of the recorder. Disinfect as needed, following instructions from your infection control department. Sani-Cloth germicidal surface wipes are recommended. Sterilization is not needed.Do not submerge the recorder or the patient lead wires in water.

Warning: The product cannot be exposed to Ethylene Oxide (EtO) sterilization processes as it may negatively impact the device and/or battery.

To Remove Belt Clip

If you need to remove the belt clip, you will need a long flat tool like a screw driver. In order to remove the clip, one has to slightly pry up the end of the clip near the battery cover while pulling the clip out. At the end of their useful lives, all NorthEast Monitoring Inc. products should be disposed of following local ordinances.

Appendix B: Maintenance and Care of Patient Lead Wires

Intended Use

This patient lead wires are intended to be used for the hook-up of a patient to an electronic medical device with the purpose of sensing electrocardiography signals from the human skin using appropriate disposable or reusable ECG electrodes. The application must be performed by a skilled medical professional. The patient lead wires are to be used for the specific purpose mentioned on the reverse only.

Instructions for Use

See safety warning on lead wires

Check the patient lead wire integrity before each use. In case of damage of any kind, do not use and do not attempt to repair. Consult your biomedical technician. If patient lead wire is found to be contaminated, clean it and disinfect it according to instructions below before reusing

Plug equipment connector into its receptacle and connect all patient lead wires to ECG electrodes suitable for your application. Make sure the electrodes and patient connectors are placed correctly following the IEC publications

Tape the patient lead wires to the skin if necessary to avoid movement artefacts. Pay attention to achieve a sensible and ergonomic cable routing

In case you experience disturbance, distortion or interruptions of the signal, stop the procedure and localize the source and, if possible, amend the problem before you continue.

At the end of the procedure, gently disconnect electrode connectors from electrodes. Be aware disconnecting the equipment connector that it could be latched. Unlatch before pulling

Store by hanging patient lead wires in big loops. Tight coiling must be avoided. Also avoid heat sources and direct sunlight.

Patient lead wires supplied are non-sterile and are reusable. For cleaning and disinfection the following substances and procedures must be used:

Cleaning

Patient lead wires can be cleaned with the following: Green soap, green soap tincture (US Pharmacopeia) or alcohol free hand soap, 2% glutaraldehyde solution (such as Cidex), sodium hypochlorite (bleach) solution 10% in water. To clean:

1. Disconnect the patient lead wires from recorder.

2. Dampen a clean cloth or gauze pad with an appropriate cleaning solution and wipe all exposed surfaces.

3. Dampen a clean cloth or gauze pad with sterile or distilled water and again wipe all exposed surfaces.

4. Dry all exposed surfaces with a clean, and dry cloth or gauze pad

Adhesive residues can be removed with the alcohols listed below. Never use other organic solvents (e.g. acetone or toluol will damage the wire jacket)!

Disinfection

First, clean patient lead wire as described above.

Perform wipe disinfection using products with the following substances as active ingredients:

- Ethyl or Isopropyl alcohol 70 – 80%
- Glutaraldehyde 2% (pH 7,5 - 8) (e.g. Cidex®)
- Quaternary ammonium compounds (e.g. Sani-cloth HB wipes)

Remove the disinfectant immediately after the recommended contact time wiping the cable with a cloth moistened in water

Sterilization

Only sterilize when necessary as determined by your hospital´s guidelines, to avoid long-term damage of the patient lead wires. The wires can withstand standard EO (EtO) sterilization cycles (1 hour, < 57°C, < 75% rel.humidity).

Make sure the correct aeration time has transpired before using the patient lead wires again.

Caution

- The materials used are not suitable for autoclave or UV sterilization
- Never immerse or soak
- Prolonged alcohol exposure can negatively affect the mechanical properties of the jacket
- N-propyl alcohol or sodium hypochlorite (bleach, Clorox) should be avoided for the disinfection

Appendix C: Batteries

The recorder uses one AA-size battery Acceptable battery types available on the market are:

- Alkaline (example: Eveready Energizer E91, Duracell NM1500)
- Heavy Duty
- Nickel Metal Hydride (example: MAHA AA 1800 mAh, Rayovac 1600 mAh NiMH)
- Nickel Cadmium (NiCd)

Alkaline

The alkaline is the most common type of battery. When a new, properly stored battery is used, a recording time of 14 days in Holter. While a recording that runs for 24 hours will in theory use less than half the capacity of the battery, using a battery for two different patients' 24-hour recordings is not recommended. The risk is that the "second" recording will not reach 24 hours.

The primary limitation of this battery type is that there is only a limited ability to test the battery before it is used. Unfortunately, at times a defective battery will appear to initially have full capacity, but will fail well before the expected time. The probability of this type of failure is very small when the batteries are obtained from the primary suppliers.

The best prevention available against defective batteries is to obtain them from suppliers who do not store them for a long time and do store them properly. There are few requirements for storage of alkaline batteries. They should be stored at "room" temperatures (50-90 F) and in a dry location. There is no advantage to storing them in a refrigerator. There is actually a significant problem with low-temperature storage. Normal refrigerators have a very high humidity inside and this can cause a much greater reduction of life that is gained by the lower temperatures. In addition, storage at a temperature below freezing will reduce battery life.

Heavy Duty

Batteries that are labeled "Heavy Duty" vary widely in capacity. The use of "Heavy Duty" batteries is not recommended.

Nickel Metal Hydride (NiMH)

This class of batteries is rechargeable and thus can be used in situations where a disposable battery is not desirable. Batteries of this type come in a range of capacities with the labeled capacity ranging from 1100 to 1800 mAh (milliamp hours). It is recommended that only batteries with a rating of at least 1500 mAh be used. Lower capacity batteries will operate the recorder for 7 days when they are new but after only a few uses may not be able to operate for the full 7 days.

Charging these batteries is the most difficult part of their use. Only standard chargers that are specifically rated for use with NiMH batteries should be used such as the MAHA MH-204F or Rayovac 1-Hour charger; although medically-approved chargers can be used, they are not necessary. Older chargers designed only for NiCd (Nickel Cadmium) will overcharge this type of battery and can significantly shorten battery life. A charger that applies an excessive continuous charge can also shorten the battery life. If in doubt it is best not to leave the batteries on charge for long periods of time after the charger indicates a full charge.

Unlike the older rechargeable battery types, NiMH batteries have no real "memory". Thus they do not need to be completely discharged or "conditioned" to insure that they will fully charge. Doing a complete discharge will reduce the total life of the battery as every time the battery is discharged below about 25% capacity, the life of the battery is shortened more than for a normal discharge cycle.

Most chargers for NiMH batteries depend on a property of these batteries that causes them to heat up when they have reached full charge. This has two consequences. First, if the batteries are being charged in pairs, the first battery to be fully charged will heat up and shut down the charge cycle. This can leave one of the batteries partially charged. Thus it is best to keep pairs of batteries together so they are both discharged and charged together. Secondly, if the battery is too warm for any reason, it

may shut down the charge early. For that reason the batteries should be charged at normal room temperatures and it is often best not to cover the batteries in any way during the charge. Even the charger's own cover may reduce the charge. Leave the cover open during charging.

When the battery is not being charged, it will slowly discharge by itself. This type of battery will lose about one percent of its charge for each day. Most chargers will bring a partially charged battery up to full capacity in under an hour. Batteries that have not been used for over two weeks should be charged before use.

If used properly, these batteries will last for 300 to 1000 recordings of 7 days each. They will still not last forever. To control battery life, writing the date on the battery that the batteries are first put in service can be helpful.

Nickel Cadmium

This type of battery has less capacity than the NiMH and is not recommended. Also, disposal of this battery can pose problems.

Battery Replacing

Insert a blunt object (for example, pen, coin or non-pointy tool) in the space between the battery and the top edge of the recorder. Press gently to easily remove the battery.

To insert a fresh battery into the battery compartment, be sure to orient it as indicated in the diagram inside the compartment. The battery sits loosely in the compartment.

Appendix D: Pacemaker Detection

The recorder has a built-in pacemaker detection capability. This was designed to overcome the problems inherent with the analysis of Holter recordings from patients with pacemakers.

A pacemaker is designed to initiate cardiac conduction by stimulating a spot on the myocardium with a pulse of 1-4 volts and a duration of typically 250 to 2,000 microseconds. When this pulse is seen at the surface recording electrodes it is significantly attenuated. For patients with a unipolar electrode configuration, the signal at the surface may range from under 50 to over 200 millivolts. When a bipolar lead configuration is used, the signal is typically much lower and is in the range of 3 to 50 millivolts. Especially with the bipolar leads, the signal size is dependent on the positions of the pacemaker lead and the surface electrodes.

The amplitude of the signal being referred to here is not the size of the "spike" commonly seen on an ECG cart or bedside monitor. Since the duration of the pulse is short compared to a QRS complex, normal ECG recorders will greatly attenuate the signal; in some cases it cannot be seen at all. Also, some ECG recorders have devices which enhance the pace pulse to insure that it will be displayed. Only very wide bandwidth recorders as are sometimes used in an electro-physiology study will show the unmodified full amplitude of the pulse.

The recorder has the wide bandwidth ECG amplifiers necessary to pass the pacemaker pulse. Since the pulse would still be too short to be recorded in a reliable manner at any practical sampling rate for Holter recording, the pulse is detected by the recorder. The time of the pulse is then digitally stored along with the Holter ECG data. When the data is analyzed, the pacemaker pulse is displayed and used for the analysis.

At recording time, it is desirable to have the recorder be as sensitive to the pacemaker pulse as possible so pulses will not be missed. A conflicting requirement is that there should be as few false pacemaker detections as possible.

False pacemaker detections are primarily caused by electrical events. Any external electrical signal that is coupled to the patient electrodes which looks like a pacemaker pulse will of necessity be stored by the recorder. The most common form of electrical signal that can look like a pacemaker signal is an elec-

trostatic discharge (ESD) or "spark." These happen very frequently in dry weather but also occur, at a lower rate, under humid conditions.

Fortunately most ESD spikes as seen at the patient electrodes are of shorter duration or of lower amplitude than the real pacemaker pulses. While there is no absolute limit to the size or duration of the ESD pulses, the recorder ignores all pulses that are less than 150 micro-seconds long or are less than two millivolts in size.

As pacemakers are normally programmed to a pulse width greater than 200 microseconds, this does not cause a loss of detection. The require-ment that the pacemaker pulse be at least two millivolts in size is not a common problem.

Appendix E: EMC Information

Attention should be paid to the following EMC information prior to installing or using the NorthEast Monitoring DR200/HE Holter Recorder device.

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of the device.
- The device has been tested and found to comply with IEC/EN 60601-1-2.
- Computers, cables and accessories not tested to 60601-1-2 may result in increased emissions or decreased immunity of the device.
- Verify normal operation if utilizing the device adjacent to or stacked with other electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The NorthEast Monitoring DR200/HE Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the NorthEast Monitoring DR200/HE Holter Recorder should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	NorthEast Monitoring DR200/HE Holter Recorders use RF energy only for its internal function. Therefore, its RF emissions are not likely to cause any in nearby electronic equipment.
RF emissions CISPR 11	Class B	NorthEast Monitoring DR200/HE Holter Recorders are suitable for use in all establishments other than domestic and those directly connected to the public low-volt-age power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The NorthEast Monitoring DR200/HE Holter Recorders are intended for use in the electromagnetic environment specified below. The customer or user of the recorder should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable. No cables exceed 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable. NorthEast Monitoring DR200/HE Holter Recorders are battery powered.	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	Not applicable. NorthEast Monitoring DR200/HE Holter Recorders are battery powered.	N/A
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The NorthEast Monitoring DR200/HE Holter Recorders are intended for use in the electromagnetic environment specified below. The customer or user of the recorder should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2,5 GHz</td><td>3 V

3 V/m</td><td>Portable and mobile communications equipment should be used no closer to any part of the NorthEast Monitoring DR200/HE Holter Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
d = 1.2$\sqrt{}$P

d = 1.2$\sqrt{}$P 80 MHz to 800 MHz

d = 2.3$\sqrt{}$P 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td>a</td><td colspan="3">Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the recorder is used exceeds the applicable RF compliance level above, the recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or recorder</td></tr>
<tr><td>b</td><td colspan="3">Over frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the NorthEast Monitoring DR200/HE Holter Recorders

The NorthEast Monitoring DR200/HE Holter Recorders are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the recorder as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	**0.23**
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix F: Extraction of ECG data on 3-channel

It is possible to retrieve the raw ECG files from the Holter files. For all 3 channel data the process results in three files, one for each channel. Each file is then in the form of a binary file consisting of 16bit words (little endian) with each word representing one sample. The sampling is at 180 samples per second. The data is scaled so that the least significant bit has a value of 12.5 uv. If a pacemaker pulse was detected, the sample at the time of detection will be replaced by the value 0x8000.

To generate these files, first analyze the data (actually the flash.dat) from the recorder using any compatible version of the Holter Analysis program. At the completion of this there will be a file "datacard.dat" in the patient directory. The full path is by default:

c:\nm\pat\xx\datacard.dat

where xx is the number of the patient dataset. This can be seen in the "No. and Directory" columns of the "File->open/new" display.

Then, change the directory to c:\nm\bin and on a single command line, run the following command using the following 5 arguments:

unpackc d1 f1 f2 f3 0

- where d1 is the path to the source datacard file, for example,
  d1= c:\nm\pat\xx\datacard.dat
- f1, f2 and f3 are the resultant binary destination files, for example:
  f1 = c:\nm\pat\xx\flashc0.dat
  f2 = c:\nm\pat\xx\flashc1.dat
  f3 = c:\nm\pat\xx\flashc2.dat

The result will be the three files in the patient directory xx described previously. The files are flashc0.dat flashc1.dat and flashc2.dat which are for channel 1,2 and 3 respectively. If desired, the destination paths for this command can be any other path but spaces are not allowed in the path or file name.